REMARKS

This submission is a second preliminary amendment and remarks filed in this continuation prosecution application prior to mailing of an official action on the merits. Claims 1-3, 5-20 and 50-65 were pending in this application. Claims 89-93 have been added herein (claims 66-88 being previously cancelled after restriction). Therefore, claims 1-3, 5-20, 50-65 and 89-93 are currently pending.

As an initial matter, Applicant wishes to recap the history of this application. In the previous application (prior to this CPA), the Examiner issued a Final Rejection on April 4, 2002. On September 4, 2002, Applicant filed a Notice of Appeal. Subsequently, on April 4, 2003, Applicant filed this CPA. The CPA was filed without payment of the filing fees. However, instead of issuing a Notice to File Missing Parts, the Office issued a Final Rejection on May 6, 2003. After interviewing the Examiner's supervisor, Ms. Corrine McDermott, she stated that the Office would vacate the May 6, 2003 Office Action and issue a Notice to File Missing Parts (see Interview Summary, Paper No. 16). The Office issued a Notice to File Missing Parts on October 20, 2003 and Applicant has filed a response along with payment of the required fees herewith.

Thus, it is Applicant's understanding and position that 1) the Final Office Action dated May 6, 2003 has been vacated; 2) there is no outstanding office action in this application; and 3) the claims are presently not under rejection. Nonetheless, Applicant is cognizant that prior to filing the CPA, the claims were under final rejection in an Office Action dated April 4, 2002 (hereafter referred to as "the previous Office Action"), and makes the following comments.

In the previous Office Action, the Examiner had rejected claims 1-3, 5-20 and 50-65 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and

distinctly claims the subject matter which application regards as the invention.[1] Each of the points raised by the Examiner is addressed in turn.

The Examiner stated that claims 20 and 51 as worded were confusing. As Applicant understands the Examiner's position, he contends that claims 20 and 51 claim nothing more than disjointed particles, and it is unclear how the disjointed particles "form a dimension to permit soft tissue growth therein." However, what claims 20 and 51 recite are soft tissue implant materials containing (comprising) particles, with the particles having "interstices therebetween having dimensions effective to permit soft tissue growth." Thus, the claims clearly define the structural and spatial relationship of the particles to one another - the relationship being that there are interstices between the particles, with the interstices being of dimensions permitting soft tissue growth. How that is accomplished is different from what structure is defined by the claims, which in any event is fully discussed in the specification (see page 8, lines 8-12).

For clams 1 and 51, the Examiner stated that the term "intraparticulate" does not find support in the specification as filed. However, that term is found in the specification, as filed, at page 5, line 8, and also in the Abstract, line 3.

The Examiner stated that claims 6 (Applicant believes the Examiner means claim 5, not claim 6) and 53 were indefinite because the "range cannot be correct." Applicant submits that there was nothing indefinite about the range because it is clearly specified using a numerical range. However, claims 5 and 53 have been amended herein to re-state the range. As these claims are not presently under rejection and the amendments merely re-state what was already present in the claims, these amendments were not made for reasons related to patentability, nor were the claims narrowed thereby.

[1] Applicant submits that as the April 4, 2002 Office Action made these rejections of originally-filed claim language for the first time, the Office Action should not have been made final.

The Examiner stated that claims 9 and 59 were indefinite because it is not clear how the material further comprises collagen, and asks whether it is part of the polymer matrix or a separate entity. First of all, it is not clear to Applicant what the Examiner means by "polymer matrix," as that term does not appear in the application. Regardless, Applicant submits that the claims are clear, as their plain meaning specifies that the soft tissue implant material recited in claim 20 and 51, also contains, *i.e.*, "further comprises," collagen. This is discussed at various places in the specification, *e.g.*, page 5, line 3, page 6, lines 9-10, page 9, lines 13-15 and Abstract, lines 7-8, and thus Applicant submits that one of ordinary skill in the art would understand what is meant by the claim. *See* MPEP § 2173.02.

The Examiner next stated that claims 12 and 62 were indefinite because it was not know what is meant by "injectable collagen." Applicant submits that the meaning is clear. The plain meaning of adjective "injectable" is that something is able to be injected. Further, injectable collagen is the common term used for a widely-known product that has been used extensively in medical and cosmetic procedures for two decades. It is discussed in detail in Applicant's specification. *See, e.g.*, page 2, lines 4-13; page 10, lines 2-3. It is inconceivable that one of ordinary skill in the art would not understand what is meant by the term "injectable collagen."

With respect to claims 18, 19 and 63, the Examiner stated that it was not clear how the bioactive element is added to the polymeric particles. However, claims 18 and 63 do not recite that the bioactive element is added to the particles. Rather, they claim a soft tissue implant material and soft tissue implant, respectively, that contains (comprises) a "bioactive substance" (in addition to the particles). Applicant notes that claim 19 recites that the bioactive substance is grafted to the particles. These claims are clear.

Finally, the Examiner stated that claims 50 and 65 are indefinite because it is unclear how the implant of the preamble of the claims further defines the structure of the implant material of

claims 20 and 51[2]. However, claims 50 and 65 do not further define structure of the implant material of claim 20 and claim 51. In fact, they do not claim an implant material all, but an implant containing (comprising) the implant material of claim 20 and claim 51, respectively. The references to claims 20 and 51 are a permissible shorthand to specify the implant materials that comprise the claimed implant. *See* MPEP § 2173.05 ("a claim which makes reference to a preceding claim to define a limitation is an acceptable claim construction"). Thus, there is nothing indefinite about claim 50 and 65.

In summary, none of the claims were, or are, indefinite under 35 U.S.C. § 112, second paragraph.

Turning the prior art rejections in the previous Office Action, the Examiner first rejected claims 51-58 under 35 U.S.C. § 102(b) as being anticipated by Bruins *et al.* The Examiner stated that Bruins discloses an implant comprising particles having a PMMA inner core with a PHEMA outer layer, and that the claims read on the intermediate product disclosed by Bruins.

The Examiner also rejected claims 1-3, 5-20 and 50-65 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,336,263 to Ersek *et al.* in view of U.S. Patent No. 4,728,570 to Ashman *et. al.*[3] The Examiner contended that Ersek discloses a particulate soft tissue implant, and it would be obvious to coat the Ersek particles with calcium hydroxide would be obvious based on the teachings of Ashman '570.

Applicant respectfully disagrees. Attached for the Examiner's consideration is a Declaration under 37 C.F.R. § 1.132 from the Applicant, Dr. Arthur Ashman, hereinafter referred to

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[2] Claim 65 has been amended herein to correct a typographical transposition error in the claim as filed.

[3] On page 5 of the previous Office Action, the Examiner discusses claim 20 with respect to Bruins. However, claim 20 has never been rejected as being anticipated by Bruins.

as "Ashman Declaration." *See* MPEP § 716.01 (such evidence must be considered by Examiner). Dr. Ashman is a named inventor on both the Bruins and the Ashman '570 patents asserted by the Examiner. Therefore, the Examiner should consider his declaration to be the best evidence of both the teachings of these references and their comparison to the present invention.

As discussed above, claim 51 does not claim an implant material, but rather, a particulate implant. Ashman Declaration ¶ 12. Bruins does not disclose this. *Id.* at ¶ 5. In contrast, Bruins teaches only sintered or bonded implants. *Id.* at ¶ 4. Further, prior to Dr. Ashman's present invention, it was unknown and unexpected that the recited material would function as a soft tissue implant in particulate form. *Id.* at ¶ 12. Therefore, Bruins does not anticipate claims 51-58 or otherwise render them unpatentable.

Moreover, during an in-person interview with Applicant and Applicant's representative on June 25, 2001, the Examiner previously assigned to this case, Ms. Choon Koh, and her supervisor, Ms. Corrine McDermott (who is also the present Examiner's supervisor), acknowledged the difference between the present invention and the prior art. The position of the Examiner and Ms. McDermott was clearly expressed on the Interview Summary (PTOL-403), which states that the invention of a particulate implant

> distinguishes from the Bruins' material with respect to the characteristics of the particles, e.g., particulate vs. molded.

See also Applicant's statement under 37 C.F.R. § 1.333(b) (Amendment dated October 24, 2001, p. 11) stating that at the interview

> the parties discussed the fact that the cited patent to Bruins discusses sintered implants, but does not teach particulate or granular implants as in the present invention.

The Examiner should follow the previous Examiner's and the supervisor's determinations. *See* MPEP § 713.01 (where "agreements were reached at the interview . . . the second examiner should take a position consistent with the agreements previously reached").

With respect to claims 1-3, 5-20 and 50-65, the Examiner's contention that it would be obvious to coat the particles of Ersek with calcium hydroxide rests upon several assumptions, including that hard tissue is the same as soft tissue, calcium hydroxide has the same interaction with soft tissue as hard tissue, and that one of ordinary skill in the art at the time of the invention would recognize conclude that calcium hydroxide is beneficial in soft tissue implants merely because it is beneficial in hard tissue implants. This is not the case.

First, there is no suggestion in Ashman '570 or any of the cited art that either the soft tissue implant as in Ersek had any disadvantages or that there would be any advantage to adding calcium hydroxide to soft tissue implants, as opposed to hard tissue implants. Therefore, there was no motivation or suggestion to combine the references or expectation of success or advantage by doing so. *See* MPEP §§ 2143.01 (prior art must suggest the desirability of the claimed invention); 2143.02 (obviousness requires expectation of success); *see also* MPEP § 2144 (no expectation of advantage to support combination or references). Applicant respectfully submits that the prior art does not establish a *prima facie* case of obviousness and that Examiner's rejection was based on improper hindsight and "obvious to try" rationale. *See* MPEP § 2145(X) (these are improper bases for obviousness rejections).

In addition, as explained by Dr. Ashman, the biological and physiological differences between soft tissues and hard tissues would not lead one of ordinary skill in art to have any expectations of benefit to calcium hydroxide in soft tissue implants. To the contrary, one of ordinary skill in the art would believe that there would be no benefit, and the invention achieved superior and unexpected results.

Ashman '570 discloses that when calcium hydroxide coated polymeric particles are implanted into hard tissue (not soft tissue), the calcium hydroxide promotes hard tissue growth. Ashman Declaration ¶¶ 6-7. The reason for this is that the calcium hydroxide interacts with bleeding marrow from the surgical site and transforms into calcium carbonate apatite. *Id.* at ¶ 7. It

is the calcium carbonate-apatite that promotes hard tissue growth and raises pH (to alkaline) to facilitate healing and reduce infection risk. *Id.*

However, in soft tissue, the calcium hydroxide does not transform into calcium carbonate apatite. *Id.* at ¶ 8. Nonetheless, calcium hydroxide stimulates soft tissue growth, including collagen production. *Id.* at ¶¶ 8, 10. Prior to Dr. Ashman's present invention, it was unknown that this would occur. *Id.* at ¶ 11. Further, due to the differences between hard and soft tissue, and that calcium hydroxide did not transform to calcium carbonate-apatite in soft tissue, it was entirely unexpected that the achieved beneficial effects would occur. *Id.*

In other words, the physiological mechanisms of tissue growth promotion by calcium hydroxide in hard tissue and soft tissue are entirely different. Further, it was known that the mechanism of tissue growth promotion in hard tissue (conversion to calcium carbonate-apatite) did not occur in soft tissue, *i.e.*, it was known that hard and soft tissues were different. In view of this, not only would one of ordinary skill in the art not expect calcium carbonate to promote tissue growth in soft tissue, but instead would have the expectation that it would not. The lack of an expectation of success and the present invention's achievement of unexpected results, *e.g.*, the unexpected property of calcium hydroxide to promote soft tissue growth in soft tissue, means that the claims cannot be obvious. *See* MPEP §§ 716.02(a) (not obvious where there is "presence of an unexpected property" in the invention); 2143.02 (claims not obvious if no reasonable expectation of success); 2144.09 (not obvious where there is "evidence of superior or unexpected results").

New claims 89-93, which have been added to more fully claim the invention, are patentable for the same reasons as discussed herein.

In view of the above, Applicants submit that the application is presently in condition for allowance, and the Examiner is respectfully requested to pass this application to issue.

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Respectfully submitted,

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